

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: WAVE 2 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION	Master File No. 2:12-MD-02327 MDL No. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE GENERAL-CAUSATION TESTIMONY OF
NATHAN W. GOODYEAR, M.D.**

MAY IT PLEASE THE COURT:

1. BACKGROUND

Nathan W. Goodyear, M.D. was the implanting physician for numerous plaintiffs in the Wave cases against Defendants, including plaintiff, Tina Morrow (No. 2:12-cv-00378), the only Wave 2 plaintiff to which defendants' Motion applies. Dr. Goodyear was retained by plaintiffs to render case-specific opinions regarding the nature and cause of Mrs. Morrow's post-Prolift and TVT-O implant injuries. Dr. Goodyear opined that Mrs. Morrow's injuries, including multiple erosions, pelvic pain, dyspareunia, repeated surgical revisions, UTIs, vaginal bleeding and vaginal discharge and odor, were more probably than not caused by the Prolift and TVT-O injuries. Defendants' Exhibit B, pp. 7-8. Dr. Goodyear further stated that had he been adequately warned about the complications associated with these devices, he would have recommended alternative procedures to Mrs. Morrow, and went on to conclude that the warnings were inadequate based upon his experience with treating post-implant injuries suffered by Mrs.

Morrow and other of his patients. *Id.* Dr. Goodyear pointed out specific reasons why, in his opinion, the warnings given by defendants in the case of Mrs. Morrow were inadequate. *Id.* Finally, Dr. Goodyear opined that the devices implanted in Mrs. Morrow did not conform to the manufacturer's express warranties and described the various misleading statements made by defendants about the products. *Id.*, pp. 8-9.

It is important for the Court to recognize that Dr. Goodyear is appearing in the Morrow case as both a case-specific expert witness and a key fact witness, and not allow defendants to limit crucial and relevant fact testimony under the guise of a misplaced *Daubert* challenge. The very "opinions" that defendants seek to suppress here are key facts germane to plaintiffs' claims of inadequate warnings and breach of express warranty. Dr. Goodyear's actual opinions are case-specific to Mrs. Morrow, and are of the very same nature as those given by other case-specific experts in this litigation, which are necessarily part and parcel of the expert opinions of case-specific experts, as well as those of an implanting and treating physician. Defendants' attempts to manipulate and broaden the nature of the opinions of Dr. Goodyear should not be permitted under these circumstances in an effort to attack his testimony on a separate and distinct basis from those already made in Mr. and Mrs. Morrow's case specifically.

2. DR. GOODYEAR IS WELL-QUALIFIED TO RENDER HIS OPINIONS BASED UPON ETHICON'S OWN STANDARDS

Whether the Court views Dr. Goodyear's opinions as case-specific or general, Dr. Goodyear's credentials more than qualify him to render the opinions given in the Morrow case. It is difficult to comprehend how Ethicon could genuinely question Dr. Goodyear's qualifications when Ethicon itself held Dr. Goodyear out to be an expert in these procedures to the medical community. Dr. Goodyear acted as a Preceptor and consultant for Ethicon from 2006 to 2009. Exhibit 1. He was paid by Ethicon to teach other doctors how to perform the very

procedures at issue in this litigation. Exhibit 2, 203:15-19. Other doctors would go into the operating room with Dr. Goodyear to watch and learn from him how to appropriately implant and treat patients implanted with Prolift and TVT products. Exhibit 1; Exhibit 3, pp. 52:19-53:12. Dr. Goodyear was certified by Ethicon in Advanced Laparoscopic Gynecological Procedures in 2003 (Exhibit 4); implantation of the Gynecare TVT*Obturator System in 2004 (Exhibit 5); and implantation of the Gynecare Prolift* Pelvic Floor Repair System in 2005 (Exhibit 6). Dr. Goodyear was a paid faculty member and presenter at Ethicon-sponsored training events designed to teach other physicians about these medical devices, the implant procedures and management of patients receiving these implants. Exhibit 7.

Defendants argue that because Dr. Goodyear has changed the nature of his practice to no longer perform gynecological surgery that he is somehow unqualified to render the opinions given in the Morrow case. However, the simple fact that an expert is retired from his proposed field of expertise does not, in and of itself, disqualify him as an expert. Neutrino Development Corp. v. Sonosite, Inc., 410 F. Supp. 529, 539 (S.D. Tex. 2006); see also Garrett v. Carpenter, No. 3:13-cv-00190, 2016 WL 1126520 (M.D. Tenn. Mar. 21, 2016). Moreover, because Dr. Goodyear was the implanter in the Morrow case, as well as an Ethicon trained/certified expert, he has particularized knowledge to render opinions relevant to the liability of Ethicon in this litigation.

Here, Dr. Goodyear has not retired from the practice of medicine, nor practice in the field of gynecology, which is pertinent to this case. Dr. Goodyear is more than sufficiently equipped to testify regarding his opinions in the Morrow case based upon his prior experience and knowledge in treating Mrs. Morrow and others with mesh-related complications. The majority of Dr. Goodyear's practice remains devoted to female pelvic gynecology. Exhibit 2, 55:23–56:6.

Dr. Goodyear continues to treat patients non-surgically for gynecological conditions found on exam, and refers out any gynecological patients needing surgical intervention. *Id.*, 201-203. Dr. Goodyear remains board certified in obstetrics and gynecology, an active member of the American Congress of Obstetricians and Gynecologists (ACOG), and abreast of the current literature as it related to gynecological conditions and treatment. Exhibit 3, 26. Dr. Goodyear saw Mrs. Morrow in his office and performed a gynecological examination prior to rendering his report. Simply because Dr. Goodyear has chosen to no longer perform surgical mesh or other gynecological procedures, does not mean that he is unqualified to testify as an expert in Mrs. Morrow's case given his credentials, vast experience in the field and treatment of Mrs. Morrow, not to mention defendants' own endorsement of Dr. Goodyear as an expert in this field. Defendants' qualms about Dr. Goodyear's qualifications are more appropriately the subject of cross-examination, if any, rather than a challenge under *Daubert*.

3. THERE IS NO BASIS FOR EXCLUDING DR. GOODYEAR'S TESTIMONY REGARDING ALTERNATIVE PROCEDURES AVAILABLE TO MRS. MORROW

Dr. Goodyear specifically offers three (3) opinions: (1) Tina Morrow's injuries were caused by the implanted Prolift and TVT-O devices; (2) The Prolift and TVT-O implanted in Tina Morrow were unreasonably dangerous due to the lack of adequate warning; and (3) The Prolift and TVT-O implanted in Tina Morrow were unreasonably dangerous because they did not conform to the manufacturer's express warranties. Defendants' Exhibit B, pp. 6-10. Again, as is abundantly clear by their plain language, these opinions are case-specific and apply only to Tina Morrow. Defendants are confusing the product design issues with Dr. Goodyear's sworn testimony that he could have (and would have) chosen to perform alternative procedures on Mrs. Morrow had he been adequately warned about the nature and severity of the complications

associated with defendants' products. Dr. Goodyear's opinions about the availability of these alternative procedures is a factual assertion/opinion based on his indisputable extensive medical knowledge at the time of implantation of alternative procedures relevant to his treatment recommendations to plaintiff, Tina Morrow, and which bears directly on specific causation and plaintiffs' inadequate warning and breach of warranty claims. This simply has no bearing on plaintiffs' design defect claims, about which other experts have given opinions and testimony.

Moreover, this argument is not properly the subject of a Daubert Motion. It is instead a legal argument that should have been raised in a motion for summary judgment, for which the deadlines have passed and defendants have made no such motion. Defendants attempt to argue that there can be no question of fact on this issue, which is clearly a summary judgment standard. Further, defendants cite a number of cases all applying the summary judgment standard but, not one applying this argument in a Daubert context. Defendants arguments on this subject are not properly before the Court, and the Motion should, thus, be denied.

4. DR. GOODYEAR'S TESTIMONY REGARDING EROSION RATES SHOULD NOT BE LIMITED

Again, it is important that the Court keep in mind that Dr. Goodyear is a principal fact witness in Mr. and Mrs. Morrow's case as Mrs. Morrow's treating and implanting physician. The testimony that defendants have selectively chosen to cite to the Court is given completely out of context. Dr. Goodyear was questioned at length regarding his informed consent process with Mrs. Morrow and other patients receiving mesh implants, and the testimony cited by defendants in fact relates specifically to Dr. Goodyear's concerns about the information that was being provided to him by Ethicon when compared to his clinical experience and what he was reporting directly to Ethicon about these inconsistencies. Exhibit 2, 126-130. As a fact witness,

Dr. Goodyear is entitled to testify about his recollection of what was told to him by Ethicon, and then be subject to cross-examination regarding the same. Defendants have brought forth no evidence to support their contention that Dr. Goodyear's memory is unreliable or even questionable.

Of great significance to this point is plaintiffs' currently pending Motion for Sanctions for Spoliation (*Morrow v. Ethicon, Inc., et. al.*, 2:12-cv-00378, Dkt. No. 159) regarding William Martin, the Ethicon Sales Representative with whom Dr. Goodyear communicated about including an erosion rate of 3-5% in his consent forms and to whom he communicated his experience of a 15-20% erosion rate despite the lower erosion rates that he was being told to include in the consents. Exhibit 2, 128:1-19; Exhibit 3, 44:23-45:4; Exhibit 9, 49:23-50:16. The present Motion is defendants' attempt to do an end-run around plaintiffs' spoliation motion and avoid any consequences concerning their destruction of evidence pertaining to Mr. Martin's communications with Dr. Goodyear. Of course, defendants would relish in the Court's exclusion of Dr. Goodyear's testimony about what warnings Ethicon told him to include in his consents and what he reported to Ethicon regarding adverse events so that they can conceal their own destruction of key evidence relevant to plaintiffs' inadequate warnings claims.

When questioned about his erosion rates, Dr. Goodyear definitively stated that his erosion rates, for those patients not lost to follow up, were 15-20%. Exhibit 2, 128:5-21. Dr. Goodyear went on to testify that while his rates were not consistent with the information being disseminated to him by Ethicon at the time, his erosion rates turned out to be accurate and were ultimately supported by the literature cited in his reliance list. Exhibit 3, 40:5-41:13; *The Use of Vaginal Mesh for Pelvic Organ Prolapse*. AUGS and ACOG Comm. Opin. No. 513, December 2011, *supra.*, cited in Dr. Goodyear's Reliance List, attached hereto as Exhibit 8. To say that

there is no objective, reliable basis for Dr. Goodyear's experience, opinions and testimony regarding his own erosion rates versus what was being told to him by Ethicon at the relevant time period is patently false.

With respect to what was being reported to Dr. Goodyear by Ethicon, Dr. Goodyear expressly stated that the 3-5% erosion rate that he included in his consent form was reviewed and approved by Ethicon's sales representative, William Martin, whose custodial file and storage unit full of information was conveniently lost or destroyed, without explanation by the defendants. Exhibit 9, 63:15-19. Dr. Goodyear also testified that he was provided with the low erosion rate statistics by Ethicon, and that at a roundtable meeting presented by Dr. Lucente in 2008 Dr. Lucente represented that he had an erosion rate of less than 1%. *Id.*, 60:17-61:12. The erosion rates quoted by Dr. Goodyear are verified by the testimony of and statements of Dr. Lucente himself. Exhibit 10, 122-129.; Exhibit 11, ETH.MESH.00067363. Furthermore, Dr. Goodyear provided literature during deposition regarding the basis for his including the 3-5% erosion rate in his consent form as per the information and instruction provided to him by Ethicon. Exhibit 3, 8:5-23; Exhibit 12. It is important to note that the authors of the studies cited by Dr. Goodyear supporting the quoted 3-5% erosion rate, Dr. Michel Cosson and Professor Bernard Jacquetin, are Ethicon consultants and inventors of the Prolift. This supports Dr. Goodyear testimony that the information and literature regarding low erosion rates was being supplied to him through Ethicon sources. Exhibit 3, 157:24-158:19.

Thus, Dr. Goodyear's testimony about defendants underreporting erosion rates, such that it had a direct impact on the warnings, information and recommendations provided to Mrs. Morrow in this case, are reliably based upon actual facts as reported by Dr. Goodyear, other witnesses and the literature. Again, defendants are inappropriately trying to limit Dr. Goodyear's

fact testimony. There is no basis for challenging the reliability of Dr. Goodyear's memory, and any such challenge is appropriately made during cross-examination. However, even if defendants' challenges to Dr. Goodyear's testimony regarding erosion rates and underreporting by Ethicon are appropriate under *Daubert*, there is a sufficiently reliable basis for his opinions and testimony to be admissible.

5. DR. GOODYEAR SHOULD NOT BE PROHIBITED FROM TESTIFYING THAT THE WARNINGS PROVIDED IN THE MORROW CASE WERE INADEQUATE

Defendants improperly take great liberties with Dr. Goodyear's use of verbiage and attempt to limit doctor Goodyear's testimony about the inadequacies in the warnings provided by misleading the Court about the verbiage used in his opinions and the context in which those words are presented. Indeed Dr. Goodyear never uses the words "Instructions for Use" or "IFU" in his report, and never limits his opinions about the inadequacies in the warnings to any specific document provided to him by Ethicon.

Instead, Dr. Goodyear refers to the inadequacies in the warnings provided to him in the directions given by Ethicon on how to perform these procedures and treat patients implanted with these devices, and testified at length about the misleading and incorrect statistics about adverse events provided to him by Ethicon. As Dr. Goodyear testified, defendants delivered this information to him through educational materials, roundtable meetings, and presentations, instructions for use, patient brochures, trainings, sales representatives, literature and conversations with other Ethicon consultants. Exhibit 2, 65:5-24; Exhibit 9, 45:13-23; 49:23-50:4. In Mrs. Morrow's case, Dr. Goodyear opines that in addition to giving warnings about risks not included in these materials, defendants should also have provided accurate and adequate warnings about the severity, frequency and responsiveness to treatment of any risks that were

warned about. Instead, as is demonstrated in Section 4 above, defendants downplayed, minimized and provided misleading information to him, even when he called it to defendants' attention that his experience with patients like Mrs. Morrow was different from what he was being told. When taken in context, Dr. Goodyear in no way limits his opinions about the inadequacies in the warnings provided by defendants strictly to the IFUs, and instead opines that the information provided by defendants, when take in toto, resulted in inadequate and misleading information about the risks involved, which directly caused harm to Mr. and Mrs. Morrow.

Furthermore, Dr. Goodyear does not provide "legal conclusions" as defendants allege. As the Fourth Circuit has explained, experts are allowed to opine as to the "ultimate issue" in a case. United States v. McIver, 470 F.3d 550, 561 (4th Cir. 2006) (citing Fed. R. Evid. 704(a)). It is only when an expert's opinion crosses over into drawing a legal conclusion that it becomes inadmissible. *Id.* Under Federal Rule of Evidence 704, "[a]n opinion is not objectionable just because it embraces an ultimate issue." Fed.R.Evid. 704(a). The Fourth Circuit has explained that the "role of the district court ... is to distinguish opinion testimony that embraces an ultimate issue of fact from opinion testimony that states a legal conclusion." United States v. Barile, 286 F.3d 749, 760 (4th Cir.2002); In re C.R. Bard, Inc., 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013).

An expert's testimony goes too far only when it tells the jury what opinion to reach on the ultimate legal conclusion; for example, whether the defendant was negligent. Berry v. City of Detroit, 25 F.3d 1342, 1354 (6th Cir.1994). The distinction is subtle, but significant. Experts may reasonably disagree about whether or not a party breached the standard of care (a fact), but there is only one answer to whether a defendant is negligent (the ultimate legal conclusion). Thus, the question with regard to admissibility under Rule 704 is whether the expert's opinions

assist the jury in understanding the evidence or determining a fact issue. The answer here is that they do.

Here, Dr. Goodyear's opinions are ultimate issues of fact: whether Ethicon sufficiently warned him and his patients of the injuries his patients have sustained, and whether the materials given by Ethicon to Dr. Goodyear and his patients made certain promises that they did not meet. Dr. Goodyear's statements on these matters are his opinions as both a fact witness and an expert witness in this matter. Therefore, his report contains medical and factual conclusions based on his medical analysis that are properly admissible, regardless of any legal term of art that may have been used.

Defendants argue that Dr. Goodyear is not competent to render legal opinions regarding the adequacy of Ethicon's warnings. However, Dr. Goodyear does not seek to render any legal opinions in this matter. The statement that Ethicon's warnings were "inadequate" utilizes common language that has the same meaning in the law as in everyday usage. However, plaintiffs recognizes that in the *Bard* litigation, the Court did not allow experts to use the certain phrases, stating that the expert would need to use "terms that do not have a separate, distinct, and specialized meaning in the law." *In re C.R. Bard*, 2013 WL 2432918, at *29. Accordingly, Dr. Goodyear, of course, will comply with whatever limits the Court places on his phrasing. Defendants will have every opportunity to ask the Court to give an instruction regarding the use of legal terms of art. Such issues place form over substance and are not truly *Daubert* issues.

An experienced urogynecologist, may testify about the risks he perceives that the [product] poses to patients and then opine that the [product's IFU] did not convey those risks. See *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D.Ill.Dec.16, 2011). Furthermore, "[D]octors are fully qualified to opine on the medical facts

and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings” Wise v. C.R. Bard, Inc., No. 2:12-CV-01378, 2015 WL 521202, at *14 (S.D.W.Va. Feb.7, 2015) (Internal quotations and brackets omitted).

Here, Dr. Goodyear will testify about the risks he perceives that the Ethicon products posed to Mr. and Mrs. Morrow, and he will opine that the Ethicon did not convey these risks. A gynecologist like Dr. Goodyear is qualified to make this comparison. *See, e.g., Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D.W.Va. July 8, 2014) (finding Dr. Blaivas, a urologist, as qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU); Wise v. C.R. Bard, Inc., No. 2:12-CV-01378, 2015 WL 521202, at *5 (S.D.W. Va. Feb. 7, 2015).

In his report, Dr. Goodyear lists the injuries suffered by Mrs. Morrow and details how and why Ethicon’s warnings were inadequate *with respect to those injuries*. Dr. Goodyear does not simply conclude that Ethicon’s warnings were inadequate. Rather, he explains why the warnings were insufficient. To attack his choice of wording is, again, placing form over substance and is not appropriate for Daubert purposes. Nevertheless, Dr. Goodyear will comply with any instruction given by the Court regarding the language that can or cannot be used at trial.

Finally, defendants assert that Dr. Goodyear should not be allowed to “opine on the state of Ethicon’s knowledge.” Any concern that Dr. Goodyear will speculate about Ethicon’s state of mind is unfounded. Dr. Goodyear has not testified, and does not intend to testify about Ethicon’s hidden motives or secret intentions. Nevertheless, Dr. Goodyear should not be precluded from relying upon the documentary evidence, the testimony of Ethicon’s executives, and his own recollection of his interaction with Ethicon representatives as to what information was available

to the company at a given time, when testifying whether that information would have impacted a doctor's decision to use the Ethicon's products if it had been made known.

Dr. Goodyear opines on Ethicon's awareness of the different risks associated with its products based upon admissible evidence and testimony. None of Dr. Goodyear's statements are analogous to the speculative and inflammatory statements made by Dr. Bob Shull in the *Bard* case cited in Defendants' Motion. Rather, as both a fact and expert witness in this matter, Dr. Goodyear opines on what was known to Ethicon that would have been important to him, or any other pelvic surgeon, to know prior to recommending implantation of Ethicon's mesh devices to Mrs. Morrow.

CONCLUSION

Based upon the foregoing, plaintiffs respectfully requests that the Court deny Ethicon's Motion to Exclude Testimony of Dr. Nathan Goodyear.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 8th day of August, 2016, I electronically filed the foregoing document with the Clerk of Court using CM/ECF system, which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ MIKALIA M. KOTT